

REMARKS

Applicants respectfully request reconsideration of the newly presented rejections of the claims of the instant application in view of the amendments above, the following remarks, and the Rule 132 Declaration submitted herewith.

I. STATUS OF THE CLAIMS

Claims 1, 3-10, 12-15, and 17-20 are presently pending and under consideration. Claims 2, 11, and 16 have been cancelled. Claims 1, 7, 10, and 17 have been amended. New claim 21 has been added. Applicants reserve the right to file a divisional or continuing application on any non-pursued subject matter.

Claims 1, 7, 10, and 17 have been amended to recite a composition comprising an extract of *Buchholzia coriacea*. Support for this amendment is provided in the substitute specification at least at page 6, line 30 through page 7, line 2. Claim 1 has been further amended to recite that the extract is provided from a source of *Buchholzia coriacea* and in an amount effective to protect the skin against various effects and stresses. Support for this amendment is found in the substitute specification at least at page 6, line 30 through page 7, line 6, through page 8, lines 14-24. Claim 10 has been further amended to incorporate the limitations of original claim 16 (now cancelled). Claim 17 has been further amended to recite that the extract is from the fruit and/or seed of *Buchholzia coriacea*. Support for this amendment is found in the substitute specification at least at page 7, lines 4-6.

New claim 21, dependent upon claim 1, provides that the source of the extract of *Buchholzia coriacea* is from the fruit or seed of the plant. Support for this amendment is found in the substitute specification at least at page 6, line 30 through page 7, line 6.

No new matter is presented. No new claims are added.

II. SUMMARY OF THE INVENTION AS CLAIMED

The presently claimed invention, in one aspect, is directed to a cosmetic or dermatopharmaceutical composition comprising an extract of *Buchholzia coriacea* and at least one auxiliary and/or additive. Importantly, the extract is present from a source and in an amount effective to (i) provide an anti-aging, anti-wrinkle, rejuvenating, and/or

revitalizing effect on stressed or tired skin, (ii) promote the repair of aged and/or photo-aged skin, (iii) provide an antioxidant effect and an appeasing and anti-irritation effect against oxidative stress and pollutants, and/or (iv) protect against UV or IR radiation (see claims 1 and 3-9).

According to another aspect (see claims 10, and 12-15), the presently claimed invention is directed to a method for the cosmetic treatment of the skin or scalp, comprising the step of administering to a patient in need thereof a composition comprising an effective amount of a plant extract from *Buchholzia coriacea*. Importantly, the method further comprises inhibiting the synthesis of melanin, decreasing the effects of skin pigmentation, stimulating the growth and/or metabolism of human fibroblasts, providing an anti-aging and/or anti-wrinkle effect, providing a revitalizing or rejuvenating effect on stressed or tired skin, promoting the repair of aged and/or photo-aged skin, promoting hair growth or the delay of hair loss, providing an appeasing and anti-irritation effect against oxidative stress and pollutants, providing a protease inhibition effect, providing an antioxidant effect, and/or protecting against UV or IR radiation.

According to yet another aspect (see claims 17-20), the presently claimed invention is directed to a method for the treatment of skin inflammation comprising the step of administering to a patient in need thereof a composition comprising an effective amount of a plant extract from *Buchholzia coriacea*. Importantly, for these claims the extract is obtained from the fruit and/or seed of *Buchholzia coriacea*.

III. REJECTION UNDER 35 U.S.C. § 112, ¶ 1 (enablement)

The Examiner rejected claims 1-20 under 35 U.S.C. § 112, 1st para., for lack of enablement, and stated that Applicants' disclosure does not contain sufficient information to allow one skilled in the art to practice the claimed invention without undue experimentation. While the Examiner acknowledges that the specification is enabling for a composition and/or method comprising an extract of the plant *Buchholzia coriacea* for treatment of skin disorders, the Examiner states that it is not sufficiently enabling to prepare a composition comprising an extract of any plant belonging to the *Buchholzia* genus.

While Applicants do not necessarily agree with the Examiner's reasons for this rejection, claims 1, 7, 10, and 17 have been amended to further the prosecution of this application. More specifically, these claims have been amended to recite that the plant extract is from *Buchholzia coriacea*. Therefore, Applicants respectfully submit that the claims as presently amended are enabled under 35 U.S.C. § 112, and respectfully request reconsideration and withdraw of this rejection.

IV. REJECTION UNDER 35 U.S.C. § 102(e)

The instant Office Action states that the claims are rejected as anticipated by Ajaiyeoba et al., *Fitoterapia* 74, pp. 706-709 ("Ajaiyeoba et al.") under 35 U.S.C. § 102(e). Applicants respectfully note, however, that Ajaiyeoba et al. is not an application for patent in the United States or a patent granted on an application for patent by another filed in the United States, and is thus not art under 35 U.S.C. § 102(e). However, to the extent that the Examiner intended to reject claims 10, 11, and 17 under 35 U.S.C. § 102(a), Applicants believe that the claims are novel for the reasons set forth below.

With respect to claims 10 and 11, while Applicants do not necessarily agree with the Examiner's reasons for this rejection, these claims have been amended to further the prosecution of this application. More specifically, claims 10 and 11 now recite the limitations of claim 16, which was not rejected as anticipated by Ajaiyeoba et al., and the limitations of which are not disclosed by Ajaiyeoba et al. Accordingly, Applicants respectfully submit that claims 10 and 11 as presently amended are novel. Furthermore, as explained in Section V. below, these claims are nonobvious over Ajaiyeoba et al. either alone or in combination with Fawzi.

With respect to claim 17, while Applicants do not necessarily agree with the Examiner's reasons for this rejection, this claim has been amended to further the prosecution of this application. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Here, claim 17 as presently amended now recites a composition comprising an effective amount of a plant extract from the **fruit** and/or **seed** of *Buchholzia coriacea*.

In contrast, Ajaiyeoba et al., discloses only the extract of *Buchholzia coriacea* stem bark. Accordingly, Applicants respectfully submit that claim 17 is novel. Furthermore, as explained in Section V. below, this claim is nonobvious over Ajaiyeoba et al. either alone or in combination with Fawzi.

Applicants respectfully request reconsideration and withdrawal of the present rejection.

V. REJECTION UNDER 35 U.S.C. § 103(a)

The Examiner has rejected previously pending claims 1-20 as obvious over Ajaiyeoba et al. in view of U.S. Patent No. 4,343,798 ("Fawzi"). Ajaiyeoba et al. relates to the antimicrobial and cytotoxicity evaluation of extracts of *Buchholzia coriacea* stem bark, and discloses that the crushed bark has been used for washing of smallpox sores. While the Examiner acknowledges that Ajaiyeoba et al. "does not disclose a composition [comprising] an additional additive and/or auxiliary such as an antimicrobial agent . . . for the treatment of skin disorders," the Examiner states that Fawzi discloses that antimicrobial agents are useful within compositions for the treatment of skin disorders, and that it would have been obvious to combine the compositions of each because they are taught to be useful for the same purpose. While Applicants do not necessarily agree with the Examiner's reasoning for these rejections, claims 1, 7, 10, and 17 have been amended to further the prosecution of this application.

Independent claim 1 as presently amended, and claims 3-9 and 21 dependent thereon, recite a composition comprising, among other aspects, the extract of *Buchholzia coriacea* from a source and in an amount effective to (i) provide an anti-aging, anti-wrinkle, rejuvenating, and/or revitalizing effect on stressed or tired skin, (ii) promote the repair of aged and/or photo-aged skin, (iii) provide an antioxidant effect and an appeasing and anti-irritation effect against oxidative stress and pollutants, and/or (iv) protect against UV or IR radiation. In stark contrast, Ajaiyeoba et al. discloses that "crushed bark" has been used for washing of smallpox sores. Applicants respectfully submit that Ajaiyeoba et al. does not suggest a composition comprising such an extract from a source and in an amount effective to provide any of the presently claimed physicochemical benefits when applied to skin.

As explained in the Rule 132 Declaration submitted herewith, a person skilled in the art would not expect that extracts from the bark of a plant would have the same active components as extracts from the fruit or seed of the same plant. As further explained in the Rule 132 Declaration, extracts from the leaves of *Buchholzia coriacea* have a high content of tannins, and thus have an antioxidant effect when applied to skin. Extracts from the seeds of the same plant, however, have an active component that provides a lightening/whitening effect when applied to skin. Thus, the state of the art at the time of Applicants' invention was such that one skilled in the art would not have been able to reliably predict the presence of an active component of an extract taken from the leaf or seed of *Buchholzia coriacea* based on the extract taken from the bark of the same plant. In turn, Applicants submit that one skilled in the art would not have been able to predict that extract taken from parts other than the stem bark of *Buchholzia coriacea* would provide any active component(s) in an amount effective to produce a quantified physicochemical property as recited by the presently claimed invention. Accordingly, Applicants respectfully submit that claims 1 and 3-9 are patentable over Ajaiyeoba et al. in view of Fawzi.

Independent claim 10 as presently amended, and claims 12-15 dependent thereon, recite among other aspects a method for the cosmetic treatment of the skin or scalp comprising administering to a patient in need thereof a composition comprising an effective amount of extract from a source of *Buchholzia coriacea* and further comprising, among other aspects, providing an anti-aging and/or anti-wrinkle effect, providing a revitalizing or rejuvenating effect on stressed or tired skin, promoting the repair of aged and/or photo-aged skin, providing an appeasing and anti-irritation effect against oxidative stress and pollutants, providing an antioxidant effect, and/or protecting against UV or IR radiation. In contrast, Ajaiyeoba et al. discloses that "crushed bark" has been used for washing of smallpox sores. As discussed above, however, and as explained by the Rule 132 Declaration, the state of the art at the time of Applicants' invention was such that one skilled in the art would not have been able to reliably predict the presence of an active component of an extract taken from the one part of *Buchholzia coriacea* based on the extract taken from the bark of the same plant. In turn, it would not have been obvious to one skilled in the art in possession of Ajaiyeoba et al. that a method of

administering extracts of *Buchholzia coriacea* would further comprise any of the above-mentioned steps produced by the administration of such an extract. Accordingly, claims 10 and 12-15 are patentable over Ajaiyeoba et al. in view of Fawzi.

Independent claim 17 as presently amended and claims 18-20 dependent thereon recite, among other aspects, a method for the treatment of skin inflammation comprising the step of administering an effective amount of an extract from the fruit and/or seed of *Buchholzia coriacea* to a patient in need thereof. In contrast, Ajaiyeoba et al. recite only compositions comprising the extract of the bark of *Buchholzia coriacea* for washing of smallpox sores. Applicants respectfully submit that Ajaiyeoba et al. is lacking in any disclosure or suggestion of obtaining an extract from the fruit and/or seed of *Buchholzia coriacea* or a method of administering a composition comprising such an extract to a patient in need thereof. Furthermore, as discussed above and as explained by the Rule 132 Declaration, the state of the art at the time of Applicants' invention was such that one skilled in the art would not have been able to reliably predict the presence of an active component of an extract taken from, for example, the seed of *Buchholzia coriacea* based on the extract taken from the bark of the same plant. In turn, it would not have been obvious to one skilled in the art in possession of Ajaiyeoba et al. to administer to a patient in need thereof a composition comprising an effective amount of a plant extract from the fruit and/or seed of *Buchholzia coriacea*. Accordingly, claims 17- 20 are patentable over Ajaiyeoba et al. in view of Fawzi.

In view of the above remarks, Applicants respectfully request reconsideration and withdraw of the instant rejection.

CONCLUSION

In view of the abovementioned amendments and remarks, and the Rule 132 Declaration submitted herewith Applicants respectfully assert that this application is now in condition for allowance. The Examiner is invited to contact the undersigned counsel in order to further the prosecution of this application in any way.

Respectfully submitted,

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